K000472

MAY 1 0 2000

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: ICU Medical
Address: 951 Calle Amanecer
San Clemente, CA 92673
CONTACT PERSON: Salvadore F. Palomares, RAC
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510(k) Summary of Safety and Effectiveness

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K000472

Trade Name: Posi-Link
Common Name: Accessory Intravenous Administration Set
Classification Name: Same

Equivalent Device: ICU Medical CLC2000 (K973167)
Baxter Interlink Injection Port (K925126; K922558; and K914048)
B. Braun/McGaw Safeline Injection Port (K931377 and K941244)

Device Description:
The Posi-Link is an injection site for access with a blunt cannula. It will be marketed as a stand-alone heparin lock, but may also be incorporated into currently marketed primary and extension IV sets. The Posi-Link consists of a pre-slit synthetic poly-isoprene septum, polypropylene cap, polyester housing, and polycarbonate poppet, silicone rubber o-ring and a stainless steel spring.

The proposed device contains a poppet that moves away from the septum when the blunt cannula is inserted. The movement of the poppet increases the internal volume of the injection site. When the blunt cannula is removed, a spring returns the poppet to its original position adjacent to the septum, expelling fluid into the vascular access device. This movement of fluid helps keep blood out of the vascular access device.

Intended Use:
The Posi-Link injection site (and sets incorporating it) is intended for use with Interlink and SafeLine blunt cannulas as an accessory to Intravascular administration sets. The Posi-Link injection site provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein or artery). The Posi-Link also provides access for the withdrawal of fluids from a patient's vascular system. This device is for use as part of a program to aid in the reduction of needle stick injuries.

Biocompatibility:
The materials used to manufacture the Posi-Link are used in legally marketed devices under comparable conditions of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2000

Mr. Salvadore F. Palomares
ICU Medical, Incorporated
951 Calle Amanecer
San Clemente, California 92673

Re: K000472
Trade Name: Posi-Link
Regulatory Class: II
Product Code: FPA
Dated: February 11, 2000
Received: February 14, 2000

Dear Mr. Palomares:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k):

Device Name: **Posi-Link**

Indications for Use: The Posi-Link injection site (and sets incorporating it) is intended for use with Interlink and SafeLine blunt cannulas as an accessory to Intravascular administration sets. The Posi-Link injection site provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter (which is inserted into a vein or artery). The Posi-Link also provides access for the withdrawal of fluids from a patient's vascular system. This device is for use as part of a program to aid in the reduction of needle stick injuries.

Concurrence of CDRN, Office of Device Evaluation (ODE)

Prescription Use ✓ or _____ Over the Counter Use
(Per 21 CNR 801.109)

Sabrina Circuite
(Division Sign-Off)
Division of Dental, Infection Control, and
General Hospital Devices
510(k) Number K000472